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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	30

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/357,375	ARTHUR ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this c mmunication appears n the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-55* is/are pending in the application.

4a) Of the above claim(s) *50-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *44-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 May 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☒ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants amendment of claims 44-49 and the addition of new claims 50-55, Paper No. 27, 5/28/2003, is acknowledged. Applicants' arguments filed on 5/28/2003, Paper No. 27, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Claims 44-55 are still at issue and are present for examination.

Election/Restrictions

Newly submitted claims 50-55 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The invention of claims 44-49 drawn to a composition comprising a number of polypeptides implicated in the expression of resistance to glycopeptides and the invention of claims 50-55 drawn to a method of preparing a composition, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the invention of the composition can be made within a bacterial cell (i.e. *in vivo*) wherein said method does not involve the mixing of the isolated individual polypeptides.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 50-55 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 44-49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Brisson-Noel et al. (Antimicrobial Agents and Chemotherapy 34(5): 924-927, May 1990).

The rejection is stated in the previous office actions, Paper No. 12, 3/27/2001, Paper No. 16, 11/2/2001, and Paper No. 25, 12/2/2002, as it applied to claims 44-49.

As was stated previously, Brisson-Noel et al. teach the cloning and heterospecific expression of the resistance determinant VanA encoding high-level resistance to glycopeptides in *Enterococcus faecium* BM4147. Specifically, they teach that the transformation of a 4-kilobase *EcoRI* fragment encoding this protein conferred vancomycin resistance in *Enterococcus faecalis* and *Bacillus thuringiensis*. Brisson-Noel et al. further teach that the nucleotide sequence upstream of the vanA protein appears to be required for full expression of the glycopeptide resistance phenotype mediated by pIP816, pIP816-1 and pAT211 (See page 925, left col., lines 11-16 and

Figure 2). In total Brisson-Noel et al. teach a 10 kb portion of DNA which confers vancomycin resistance in transformed bacteria.

One of ordinary skill in the art at the time of filing would have been motivated to sequence the entire isolated 10 kb DNA fragment responsible for vancomycin resistance and identify each open reading frame and express the encoded proteins such that these proteins could be used in determining the mechanism of action in determining vancomycin resistance. The motivation for the identification and purification of these additional protein determinants is given by Brisson-Noel in there statement that there appear to be additional determinants "... required for full expression of the glycopeptide resistance phenotype..." One would have had a reasonable expectation of success based on the level of skill in the art at the time with respect to protein expression and purification.

Applicants submit that there is no evidence of record that prior to the present invention that the claimed compositions of proteins were known nor is there evidence that one could, in fact, determine the composition of proteins. In supporting applicants position applicants submit that the present claims are drawn to a specific combination of proteins such that this composition of proteins confers resistance to glycopeptides in Gram-positive bacteria. Applicants submit that while Brisson-Noel et al. disclose cloning a 4kb an 6kb EcoR1 fragments of a plasmid which confers high level glycopeptide resistance in *Enterococcus facium*, Brisson-Noel et al. does not provide any description as to what those determinants may be particularly what those sequences would be. Applicants submit that at best the Brisson-Noel et al. publication

is an invitation to experiment to try to identify the possible determinants for conferring vancomycin resistance. Applicants further submit that Brisson-Noel et al. does not in any way suggest or provide the requisite expectation that three proteins would be required for the resistance activity.

Applicants further argue that even assuming for arguments sake that applicants concede that one would have been motivated to sequence and identify the coding regions, the Brisson-Noel et al. publication does not, nor could (not), enable one to sequence the entire sequence of the plasmid, to search for the coding regions because the plasmid and the bacteria from which the sequences were originally isolated were NOT in the public's possession and thus the public could not practice the invention.

Applicants argument is not found persuasive. Applicants argument that the plasmid and the bacteria from which these sequences were originally isolated were NOT in the public's possession and that it was not until filing and publication of the application to which the present application claims priority, that the sequences themselves became available to the public is not found persuasive because applicants have not presented any evidence showing that in fact the plasmid and bacteria were not publically available at the time of invention (See M.P.E.P. Section 2121.01). In support of the office's position, that the plasmid and bacteria were publically available, applicants attention is directed to a number of different publications published by a number of different scientific groups that also were in possession of the cited plasmid and bacteria (See enclosed references by Roper et al., Tremlett et al., Kwalec et al. and Darini et al.). It is acknowledged that many of these groups received the above referred

to bacteria and plasmid from the Brisson-Noel Group., hence the strain *Enterococcus faecium* BM4147 as well as the plasmid pIP816 were publically available and the rejection is maintained.

Remarks

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
August 4, 2003